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Registration Decision

RD2011-09

Sulfentrazone

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Registration Decision for Sulfentrazone Technical Herbicide

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and its Regulations, is granting full registration for the sale and use of Sulfentrazone Technical Herbicide and Authority 480 Herbicide containing the technical grade active ingredient sulfentrazone for use on chickpeas in the Prairie provinces to control a variety of weeds.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

The detailed review for Sulfentrazone Technical Herbicide and Authority 480 Herbicide can be found in Evaluation Report ERC2010-08, *Sulfentrazone*. These products were proposed for registration in the consultation document.¹ Proposed Registration Decision PRD2011-01, *Sulfentrazone*. This Registration Decision² describes this stage of the PMRA's regulatory process for sulfentrazone and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-01. This decision is consistent with the proposed registration decision stated in PRD2011-01.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2011-01, *Sulfentrazone* and ERC2010-08, *Sulfentrazone*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable³ if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value⁴ when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in

¹ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

² "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

³ "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Sulfentrazone?

Sulfentrazone is a selective soil applied herbicide, namely, a herbicide applied before the crop and weeds have emerged from the ground. It belongs to the triazolinone chemical class and controls plants by disrupting cell membranes.

Health Considerations

Can Approved Uses of Sulfentrazone Affect Human Health?

Sulfentrazone is unlikely to affect your health when used according to the label directions.

Exposure to sulfentrazone may occur through diet (food and water), or when handling or applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 300-times higher (and often much higher) than levels to which humans are normally exposed when products containing sulfentrazone are used according to label directions.

Although the skin sensitization study did not show any effects, the dose selection for that study was not considered to be adequate according to the guideline used. As such, the technical grade active ingredient, sulfentrazone, was considered to be a potential skin sensitizer. Therefore, the label statement "Potential Skin Sensitizer" is required. Also, sulfentrazone was considered to be moderately toxic through the oral route, but of low toxicity through the dermal and inhalation routes. Although sulfentrazone was found to be minimally irritating to the eyes, it was not found to be irritating to the skin. The end-use product, Authority 480 Herbicide, was of low toxicity through the oral, inhalation and dermal routes. It was not irritating to the skin or to the eyes and was not considered to be a potential skin sensitizer.

Sulfentrazone was not considered to be genotoxic or cause cancer in animals. However, there were some indications that sulfentrazone caused damage to the developing fetus and the reproductive system. Although sulfentrazone did not cause irreversible nervous system damage, it was considered to cause some neurotoxicity at doses causing other serious effects such as mortality. Health effects in animals given sulfentrazone on a daily basis for prolonged periods of time included clinical anaemia, liver and kidney effects. There were also effects on body weight and body weight gain.

The risk assessment was conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children, nursing mothers and women of child bearing age). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most sulfentrazone relative to body weight, are expected to be exposed to less than 53.7% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from sulfentrazone is not of concern for all population subgroups.

Aggregate (food and water) dietary intake estimates for women aged 13–49 years was 21.13% of the acute reference dose and for the general population, it was 0.77% of the acute reference dose, which are not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using sulfentrazone on asparagus, cabbage, horseradish, dry shelled beans, dry shelled peas, mint, soybean and sunflower, and in Canada, on chickpeas were acceptable. The proposed MRLs for sulfentrazone in Canada in or on food can be found in the Proposed Maximum Residue Limit PMRL2010-32, *Sulfentrazone*.

Occupational Risks from Handling Authority 480 Herbicide

Occupational risks are not of concern when Authority 480 Herbicide is used according to label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply, as well as field workers re-entering freshly treated fields, can come in direct contact with Authority 480 Herbicide residues on the skin. Therefore, the label specifies that anyone mixing or loading Authority 480 Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. Anyone applying Authority 480 Herbicide must wear a long-sleeved shirt, pants and shoes plus socks. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expected exposure period for handlers and workers, risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens when Sulfentrazone is Introduced into the Environment?

Sulfentrazone is persistent in soil. Soil residues are expected to carry over to the following growing season and have a high potential to leach to groundwater. The extent to which sulfentrazone leaches and/or persists in soil is related to soil texture, organic matter and soil pH. Based on results of field studies, sulfentrazone is persistent in groundwater but is only slightly persistent in surface water ecosystems. Without risk-reduction measures, sulfentrazone may impact non-target terrestrial plants adjacent to the treatment area.

Sulfentrazone enters the terrestrial environment when used as a herbicide on chickpeas in the Prairie provinces. Once in the terrestrial environment, sulfentrazone is persistent with the only route of transformation being slow aerobic biotransformation. Field studies show that sulfentrazone will carryover to the following use season. Sulfentrazone and the degradate, 3 carboxylic acid sulfentrazone (SCA), have properties which suggest they are highly mobile and have a high potential to leach. Soil properties such as texture, organic matter and pH influence soil mobility. Under alkaline conditions ($\text{pH} > 6.5$), sulfentrazone will be more susceptible to leaching. Field studies confirm that sulfentrazone leaches and slowly transforms to SCA with depth, and that both sulfentrazone and SCA may persist for an extended time in groundwater.

Sulfentrazone can enter aquatic ecosystems through spray drift and/or runoff from treated fields. In surface water ecosystems, sulfentrazone remains in the water column and is very susceptible to phototransformation. Based on field studies, it is not expected to persist in surface waters. Sulfentrazone does not bioconcentrate and is therefore unlikely to bioaccumulate.

The risk to the environment was assessed for the end-use product, Authority 480 Herbicide. Sulfentrazone is not expected to pose a risk to aquatic organisms and terrestrial invertebrates, birds and mammals. A risk to terrestrial plants was identified and can be mitigated with spray buffer zones.

Additional information was submitted and reviewed to address the data gaps identified in ERC2010-08. No additional information is required.

Value Considerations

What is the Value of Authority 480 Herbicide?

Authority 480 Herbicide (Group 14) provides an alternative mode of action to commonly used herbicides for chickpea.

Authority 480 Herbicide, containing the active ingredient, sulfentrazone, at 480 g/L of product, is applied to bare land as a pre-plant or pre-emergence application (spring only) on the soil surface to provide control of common lamb's quarters, redroot pigweed, kochia and wild buckwheat in chickpea at a rate of 105 to 140 g a.i./ha in medium and fine textured soils in the Prairie provinces only.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Authority 480 Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing or loading Authority 480 Herbicide and doing clean-up and repairs must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. Anyone applying the product must wear a long-sleeved shirt, long pants and shoes plus socks. The label also specifies that workers not enter treated fields for 12 hours and apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal, taking into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings.

Environment

Currently, spray buffer zones of one metre are required to protect terrestrial plants from sulfentrazone spray drift. As sulfentrazone is persistent and will carry over in soil, it is recommended that any product containing sulfentrazone not be used in areas treated with this product during the previous season. To advise the user of the potential for leaching, advisory statements are included on the label.

Value

To minimize carry over of sulfentrazone, due to the persistence of the active ingredient in soils of certain textures, Authority 480 Herbicide is to be applied once every 24 months only and should not be applied:

- on any coarse textured soils;
- on fine textured soils with less than 1.5% organic matter;
- on any type of soil with an organic matter content greater than 6%; or
- on soils with a pH of 7.8 or greater.

Registration is limited to the Prairie provinces for use on chickpea. Precautionary label statements are required regarding the intervals between application and regarding re-cropping intervals.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-01, *Sulfentrazone* and ERC2010-08, *Sulfentrazone*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by email (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.